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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,185	10/18/2001	Johan Adriaan Marc Grooten	DECL1.001DV1	4839

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,185

Applicant(s)

GROOTEN ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 25, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11, 14 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11, 14 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's election of Group I with species election of anti-interleukin 15 antibody in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The office acknowledges the receipt of the substitute specification in Paper No. 3, the substitute specification rearranges the position of the figure legend in the specification.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 1, is attached to the instant Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enhancing the survival of memory T cells after exposure to an antigen with IL-15, does not reasonably provide enablement for treating an immune deficiency disease (such as HIV) by administering anti-IL15-antibodies. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant's claim is drawn to administering an anti-IL-15 antibody to a mammal and the administration of the is agonist will reduce the circulating memory cells in the mammal. Grabstein et al. (U.S. Pat No. 5,892, 001) indicates that in an immune deficiency disease condition such as the one caused by HIV infection it is desirable to activate (not suppress) the immune response by administering IL-15 (see Grabstein et al.; U.S. Pat No. 5,892, 001; column 20, lines 45-65). The lack of working examples, lack of guidance in the specification and the prior art regarding suppression of the immune system is as being desirable for treating an immune deficiency disease, greatly reduces the probability that one of skill In the art would successfully obtain the claimed invention without undue experimentation. Based on the information disclosed in the specification the ordinary artisan could not conclude that a suppression of the memory cells of the immune system will achieve a method of treatment of an immune deficiency disease. Therefore, the instant invention is not enabled for the claimed scope of treatment of an immune deficiency disease by administering an anti-IL-15 antibody.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 9-11, 14 and 18 rejected under 35 U.S.C. 102(e) as being anticipated by Grabstein et al. (U.S. Pat. No. 5,795,966).

The instant invention is drawn to a method of treating a mammal by administering an IL-15 inhibiting or eliminating compound, in this instance the inhibiting or eliminating compound is an anti-IL-15 antibody.

The recitation of the intended use recited in the preamble of the claimed method is not given patentable weight. The preamble is not given the effect of a limitation unless it breathes life and meaning into the claim. In order to limit the claim, the preamble must be "essential to point out the invention defined by the claim." *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In this instance the limitation "suppressing formation of memory cells of the immune system of a mammal" does not add a substantive step to the administration of the anti-IL-15 antibody.

The mere recitation of newly-discovered function or property, inherently possessed by things in the prior art, does not cause the claim drawn to those things to distinguish over the prior

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art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977), *In re Schreiber* 44 USPQ2d 1429).

Grabstein et al. discloses the use antagonists, anti-IL-15 antibodies, in a method of treating a disease or condition in which a reduction in IL-15 activity on T cells is desired. Such diseases include organ transplant rejection, graft versus host disease, autoimmune disease, rheumatoid arthritis, inflammatory bowel disease, dermatologic disorders, insulin-dependent diabetes mellitus, ocular disorders and idiopathic nephrotic syndrome/idiopathic membranous nephropathy (see column 3, lines 5-35). The reference discloses antibodies against IL-15 see claims. Therefore, the instant invention is anticipated by Grabstein et al.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



ULRIKE WINKLER, PH.D.
PATENT EXAMINER

10/31/03